Original article

Minimally-invasive procedure for pelvic leak points in women

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Abstract

Objective: Pelvic leak points (PLP) may be responsible for vulvar, perineal and lower limb varicose veins in women. Perineal (PP), inguinal (IP) and clitoral points (CP) surgical treatment under local anesthetics as defined by Claude Franceschi1-2-3 is a new therapeutic option. The objective of this study was to assess the reliability and durability of the PLP reflux ablation by the mean of mini-invasive surgical disconnection.

**Material:** 250 PLP in women free of pelvic congestion syndrome but with symptomatic or visible varicose veins: PP (n= 158), IP (n = 88), CP (n=4).

Methods: Open-label trial. The diagnosis and surgical skin marking of the PLP were performed by Duplex Ultrasounds. The mini-invasive treatment consisted of surgical division and non-absorbable suture of the refluxing veins and fascias, under local anesthesia.

**Follow up:** 12 to 92 months (Mean = 30.51 months).

Results: 245 (98%) without PLP reflux redo. 5 (2%) PLP reflux recurrences (PP =3, IP = 1, CP 1). Only 1 redo surgery for PP recurrence.

Conclusions:

This study suggests the reliability and durability of mini-invasive surgical treatment of the PLP and the no necessary previous pelvic varicose embolization in absence of clinical pelvic congestion syndrome.

Key Words: pelvic leak points (PLP), inguinal point (IP), perineal point (PP) clitoral point (CP

**Introduction:**

The objective of this open-label trial was to assess the reliability and durability of the ablation of the pelvic leak points (PLP) reflux responsible for vulvar and/or lower limbs varicose veins, by the mean of mini-invasive surgical treatment , without pelvic incompetent veins embolization in women free of clinical pelvic congestion syndrome.

**Background**

 Several studies4-6 consider pelvic leaks responsible for around 10% of varicose veins in women, particularly during and after one or more pregnancies7 and for 17% of the post-stripping varicose recurrences8. By the mean of Duplex Ultrasounds Scan (DUS), Claude Franceschi detected three different main pelvic leak points (PLP) responsible for vulvar and lower limbs varicose veins1-2-3-5. These PLP are called perineal points (PP), inguinal points (IP) and clitoral points (CP) (Fig 1). The Perineal Point (PP) is the superficial perineal fascia hole crossed by the superficial perineal vein which receives the anterior labial vein then flows to the internal pudendal vein. The inguinal Point (IP) is the superficial ring of the inguinal canal crossed by the mons veneris veins which connects to the uterine round ligament vein8-9-10-11. The Clitoris Point (CP) is the anastomotic plexus between the bulbar vein and the superficial dorsal clitoris vein through which the external pudendal vein and dorsal clitoris vein connect to the internal pudendal vein**12**.The reflux of these PLP veins flows back randomly to the perineum and lower limbs superficial incompetent ipsilateral but also contralateral veins, through the numerous and variable anastomosis of the superficial venous network. The PLPs represent the escape points of the shunts type IV an V according to the Teupitz CHIVA classification15.Since the PLP reflux is fed by the incompetent hypogastric tributaries and/or ovarian veins, some authors suggest the embolization of the later as a first step treatment when they are responsible for peripheral varicose veins 13-14.

Material:

250 consecutive PLP mini-invasive open surgery were performed from 2003 to February 2016 in women free of pelvic congestion syndrome but with symptomatic or visible vulvar and/or lower limbs varicose veins. The PLPs consisted of PP (n= 158), IP (n = 88), CP (n=4).

Methods

The open-label trial was conducted in a single center by the same surgical team who performed ultrasound diagnosis, mapping and pre-operatory marking as well as all the procedures.

A written informed consent was provided to the patients.

The assessment was performed with DUS 10-18 MHz linear probe and PRF set between 0.75 and 1 KHz.

The diagnosis was confirmed by a venous reflux evoked at the PLP sites by the Valsalva Manoeuver in standing women, above the safeno-femoral junction for the IP, medially to the later for the CP and the posterior quarter of the vulvoperinal fold for the PP.

An echo guided pre-operative skin marking of the PLP locations was performed.

The local anesthesia consisted of 3 ml of a mixture of lidocaine (2%) and ropivacaine (7.5 mg/dl).

The skin incision, according to skin marking, was around 10 mm for the PP and 20 mm for the IP.

 Then was performed an accurate and gentle dissection because of the of the refluxing vein fragility and in order to preserve the Perineal and Genito-crural nerves respectively at the PP and IP. Then a venous division and suture of the fascia were performed with non absorbable thread. These procedures were associated at the same time or later with additional disconnections tailored to each specific hemodynamic configuration according to the CHIVA strategy and tactics15-16-17-18-19.

A washing with a rifampicin solution had been done in every surgical procedure, without any systemic antibiotic therapy. All patients wore elastic stockings for 4 weeks, and took Enoxaparin 4000 IU. for 10 days. We recommended the use of paracetamol (1g tablet) in case of pain. All patients were checked out 8 days after surgery.

**Follow-up**

The 12 to 92 months (Mean = 30.51 months) follow up consisted of DUS assessing the long term persistence of the surgical ablation at the PLP of the pelvic venous reflux.

**Results:**

The controls didn’t find reflux recurrence was found in 245 procedures (98%) among all the controlled 250 treated PLP. 5 ( 2%) refluxes were detected: 3 ( 1,9%) of PP=158 , 1 (1,1%) of IP=88, 1(25%) of CP=4.

 Only in one patient with a PP reflux recurrence was done.

It was not observed any deep vein thrombosis, pulmonary thromboembolism, or death. Nor bruises, subcuta­neous inguinal or perineal hemorrhage, neuralgia, wound infection and superficial phlebitis, except one immediate post operative inguinal bleeding.

**Conclusions**

This study shows reliability and durability of the echo-guided mini-invasive surgery of the pelvic leaks responsible for vulvar and/or lower limbs varicose veins, without any need of pelvic incompetent veins embolization which might be indicated only in case of associated clinical pelvic congestion syndrome20-21. It stresses the necessary quality of the DUS assessment technique as well as the surgical procedure.

 Fig. 1. Frontal view of the pelvis passing through the perineal and inguinal leak points (points *P* and *I*). Note the number of anastomoses (*A*). *1*, vena ovarica (ovarian vein); *2*, tuba uteri vena (fallopian tube vein); *3*, vena uterine (uterine vein); *4*, vena iliaca interna (internal iliac vein); *5*, ligamentum teres uteri vena (round ligament vein of the uterus); *6*, vena pudenda interna (internal pudendal vein); *7*, vena rectalis inferior (inferior rectal vein); *8*, vena pudenda interna rama (internal pudendal branch vein); *9*, vena perinea (perineal vein); *10*, vena femoralis (femoral vein); *11*, vena saphena magna (greater saphenous vein); *12*, vena pudenda externa (external pudendal vein).

 the belief that his study shows the possibility of a peripheral parietal mini-invasive surgical therapy to treat reflux of pelvic origin responsible of varicose veins of the lower limbs in absence of pelvic congestion syndrome. This study even suggests that pelvic varicose embolization prior to PLP reflux ablation is not necessary. The embolization could be indicated only in case of resistant PLP reflux or symptomatic pelvic congestion syndrome. The accurate ultrasound assessment of each specific pelvic leak as well as a special minimally invasive surgical technique (ambulatory patient, local anesthesia, non-absorbable suture of vein stumps and fascias, low surgical risk and low percentage of complications) seems to be the key for satisfactory outcomes.

Since the occurrence of that bleeding we have been performing a double ligation (non absorblable overcoated ligation with the addition of a transfixed polypropylene stich).

 in uniparous or multiparous women free of symptomatic pelvic congestion syndrome (no increase of transmural pressure in venous plexuses and consequently absence of chronic pelvic pain due to vein dilation), partly or totally responsible for lower limbs varicose veins, in absence of prior or secondary pelvic veins embolization and regardless of the degree and configuration of the varicosities. The efficacy of the interventions was measured by ultrasound examination searching for reflux recurrence along time at the treated PLP level. Clinical data allow diagnosis of vulvar and perineal varices but cannot determine the leak point, since leakage from I, P or C points lead to the same clinical manifestations. A full color duplex scan allows precise identification of I, P and C points. The specific criteria of reflux at the PLP was a Valsalva descending flow provoked by having the women blow into a blocked straw while standing. Conversely, the diastolic flow at the descending tributaries of the Great Saphenous Veins (GSV) arch evoked by calf squeezing or Paranà maneuver (or every dynamic gravitational test) is not specific and may be present in the absence of refluxing PLP, so it is a source of false positives. Continuous reflux at rest (without any dynamic maneuver) may be due to a collateral compensatory draining flow caused by a downstream obstacle and thus prohibits any disconnection. It was completed by an exhaustive ECD in order to achieve a complete hemodynamic mapping of the venous insufficiency. With the patient in a standing position, IP can be located approximately 1 to 3 cm above the femoral vein and just medially to the epigastric vein and artery, at superficial ring of the inguinal canal and CP medially to the SFJ towards the clitoris. The reflux is seen outwards throughout the inguinal canal (Photo1a-1b). PP is generally located at the junction of the posterior fourth and anterior three-fourths of the labia majora. It can be detected if the patient is in a standing position with her foot resting on a platform 20 cm high or in a lithotomy position for a transperineal ultrasound (not intravaginal because the probe imaging would be too deep compared to the superficial PP). The reflux activated by Valsalva maneuver induces backflow from the Alcock’s canal to the perineal and labial veins (Photo 2). The Alcock’s canal is located medially to and just above the ischiopubic branch. The study was conducted in a single center by the same surgical team who performed ultrasound diagnosis, mapping and pre-operatory marking as well as all the procedures. A Valsalva reflux transmitted to the venous lower limbs network whatever the diameter of the veins al the PLP level( vein plexus at the IP from 5 to 15 mm, and vein at the PP from 1.8 to 3 mm diameter) in presence of visible or symptomatic varicose veins was the indication for the surgical disconnection. All patients with congenital venous disease, VVs secondary to prior deep vein thrombosis, previous PLP sclerotherapy, associated systemic pathologies, those who refused surgical treatment, who could not participate in long-term follow-up or had given birth less than 9 months previously were excluded from the study. A written informed consent was provided to the patients. The diagnosis was assessed with Echo-Color-Doppler (ECD) by the surgeons thanks to a 10-18 MHz linear probe. The PRF was set between 0.75 and 1 KHz, capable of detecting even low-speed reflux from 0.05 to 0.10 m/s. The patients were ambulatory. The same surgeon performed all the preoperatory B/mode marking and inter­ventions. The anesthesia was local: less than 3 ml of a mixture of lidocaine (2%) and ropivacaine (7.5 mg/dl). The skin incision, according to skin marking, ranged from a mean of 10 mm for the PP to a mean of 20 mm for the IP. Effective treatment of lower extremity superficial venous reflux of pelvic origin can only be achieved by ligation of the leak points in the same way as is necessary to ligate a refluxing perforating vein or junction. Proximal or distal ligation without ligation at PP and/or IP will be followed by recurrence due to collateral flow. The perineal and inguinal leak points (points *P* and *I*) act as perforating veins. Remote disconnection invariably fails either immediately or secondarily because of the presence of many branches and anastomoses (Fig. [2](http://link.springer.com/article/10.1007/s10016-004-0180-9/fulltext.html#Fig2))2. Perineal and genito-crural nerves were preserved respectively at the PP and IP. Division and stump ligation of the refluxing vein with non-absorbable braided coated suture and additional polypropylene 6 zero monofilament transfixed suture for the PP, and 4 zero for the IP. The fascia hole of the posterior labial vein was also closed with a No six zero polypropylene suture, and also the diameter of the subcutaneous ring respecting the inguinocrural nerve, with a N0 4 zero polypropylene suture. Along time we have changed the surgical technics for the IP treatment and instead of the suture of the subcutaneous ring of the inguinal canal we are now used to positioning the stump of round ligament inside the inguinal canal, with a rotation of at least 90 degrees of the plexus to the upper abdomen, fixing it to the oblique external muscle fascia with a non absorbable polypropylene stich. This procedures were associated at the same time or later with additional shunt disconnections and gravitational hydrostatic pressure segmentation tailored to each specific hemodynamic configuration according to the CHIVA strategy16-19. A washing with a rifampicin solution had been done in every surgical procedure, without any systemic antibiotic therapy. All patients wore elastic stockings for 4 weeks, and took Enoxaparin 4000 IU. for 1 to 2 weeks. We recommended the use of paracetamol (1g tablet) if they were having pain. All patients were assessed 8 days after surgery. The efficacy of the intervention (the primary end point) was evaluated checking the Doppler response provoked by the Valsalva maneuver at the treated PLP. Reflux was considered a failure, no reflux was considered a success. Diagnosis, and follow up where performed by same surgeons

Results

274 consecutive female PLP participated in the study from 2003 to February 2016 among 4209 CHIVA procedures for lower limbs varicose veins The follow-up period was from at least 12 to 92 months (Mean = 30.51 months). A total amount of 274 PLP ablation procedures had been done: PP (n= 170), IP (n = 100) and CP (n=4). Only 250 procedures with at least 1 year follow up were included in this study (158 PP, 88 IP, 4 CP), excluding 24 procedures with a follow up of less than 1 year (12 PP, 12 IP). Among all the controlled PLP no reflux redo was detected in 245 procedures (98%) where the PP were 155, the IP 87, the CP 3. Pelvic leak reflux redo was detected in 5 procedures (2%) where PP =3 (1,2%), IP =1 (0.4%), CP 1(0.4%). Taking into separate consideration each PLP the recurrence rate was 1.89% for the PP, 1.13% for the IP, 25% for the CP. Only in one patient with a PP symptomatic reflux recurrence a redo surgery was done. No deep vein thrombosis, pulmonary thromboembolism, or death occurred and considering possible surgical complications (bruises, subcuta­neous inguinal or perineal hemorrhage, neuralgia, wound infection and superficial phlebitis), there was only one inguinal bleeding (immediate surgical exploration of the inguinal canal and hemostasis thanks to a vessel legation).

Since the occurrence of that bleeding we have been performing a double ligation (non absorblable overcoated ligation with the addition of a transfixed polypropylene stich).

Discussion

The experience achieved in haemodynamic duplex evaluation showed the possibility of detecting reflux during the systolic phase of the Valsalva maneuver at well defined parietal leak points in female as well in male. Among all the surgical procedures performed according to the CHIVA strategy the pelvic escape point treated until February 2016 were 305, representing the 7.2% of all the escape point treated both in female and male. This is the reason why every haemodynamic evaluation in case of varicose veins of the lower limbs should check for valsalva reflux of pelvic origin. Ablation therapy for varicose veins of the lower limbs in presence of misunderstood PLP reflux leed to certain and anarchical varicose recurrence due to the absence of main direct re-entry path. Perfect identification of the refluxing PLP and preservation of a draining GSV represent in our opinion the best therapeutic solution to improve results along time. We now know, thanks to Claude Franceschi studies, that at least 6 well defined anatomical PLP exist for each side, and the ecoduplex identification is possible as well as the preoperative B-mode marking and surgical treatment. In our experience PLP are detected above all in women (91,2%) , but even in the male (8,8%). Considering only the female PLP andoubtedly the PP are the most frequently detected (170) followed by the IP (100). Thanks to the haemodynamics investigastion a refined functional and anatomical evaluation of the each PLP is possible and consequently so is a surgical treatment with a miniinvasive approach under local anesthesia. The aim of this surgical parietal approach is the elimination of the leak point with a low risk procedure, without any invasive manoeuvre. Differently embolization needs a main venous access, including subclavian, brachial, femoral transjugular approaches, radiation protection for patients and staff, and complication due to deep venous puncture as well as to emobolization like haematoma, pneumothorax, emobilization of non target vessels, coils migrations, pulmonary embolism, stroke had been described20. The surgical division of the veins at the fascia hole level and the suture of the fascia hole for the PP, and the suture of the stump of division of the round ligament to the external oblique muscle fascia, or the simple division of the veins of this plexus with the proximal stump maintained inside the inguinal canal far from the other stump of division for the IP, allows a low rate of recurrences along time. The surgical division of the CP is not possible close to fascia hole level because of the possibility of nervous lesions and sequelae and so in our experience was done only at the subcutaneous fascia level and for this reason the percentage of recurrence is high as expected. Fortunately the clitoral escape point is rear and the maintainance of a draining GSV help to minimize the clinical impact of the reflux as the GSV act as a re-entry path. Practically the therapeutic strategy consists in the separation of different venous compartment, and surgery may represent the instrument to applay the strategy. This study suggests that pelvic varicose embolization prior PLP reflux ablation is not necessary and indicated only in case of resistant PLP reflux or when PLP is associated with symptomatic pelvic congestion syndrome. This agree with Rabe’s literature review conclusions21. On the other hand, prior pelvic vein embolization leaves behind a PLP reflux, even if reduced, which may needs complementary superficial treatment20. Sclerosing agents and foam are also used to treat the PLP by injecting the extra pelvic veins. No long term study has been published so far. This study doesn’t report the additional CHIVA disconnections nor their specific outcomes because they don’t determine the persistence of the PLP treatment. The low rate of failures may be due to the surgical technique: veins division-ligation and fascia/superficial inguinal channel suture with no absorbable monofilament suture, which is supposed to avoid both collateral reflux and neoangiogenesis (inflammatory reaction to absorbable suture), as well as the accurate ultrasound detection of the leaking points that allows for a very minimally invasive operation. In order to improve result the preoperative B-mode marking is critical expecially for the PP treatment. Infact the posterior labial vein is really small and with the patient in a supine position it may be difficult to identify. Furthermore even the reflux is reduced in supine position. For these reasons we are firstly used to marking the PP with the patient in standing position and then we refined the marcage with the patient in gynecological position. A further B-mode check is advisable in the operating theatre (gynecological position) before the anesthetic solution injection. The Valsalva is the haemodynamic manouvre necessary to check the PLP, starting the examination at the SFJ level and following the valsalva reflux towards the strategic anatomical area: the inguinal, the perineal and gluteal area. A learning curve is necessary to perform a correct haemodynamic evaluation.

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Fig. 1. Inguinal, crural and perineal regions: IP,PP,CP position and schematic representation of the possible reflux paths

Fig. 2. Ligation of leak points. Inguinal point (IP) on the top (2a) and perineal leak point (PP) down (2b). They act as perforating veins. Their remote disconnection, represented on the left side, invariably fails either immediately or secondarily because of the presence of many branches and anastomoses. The correct ligation level is represented on the right side: subcutaneous ring of the inguinal canal close to the oblique external muscle fascia and vulvar fascia hole for the P point

Photo1a: the venous plexus of the round ligament in the inguinal canal, its relationship with the epigastric vessels (EV Vein and EA artery), the internal ring (IR), the subcutaneous ring (SR) through which a pelvic reflux is transmitted during Valsalva to the lower limbs. The external oblique muscle fascia is the hyperechoic line above the plexus, while the hyperechoic line corresponding to the trasversalis fascia is clearly visible below it.

Photo 1b: Valsalva maneuver. Clearly detectable reflux from the deep pelvic plexuses towards the surface through the inguinal canal and its superficial rin

Photo 2: Valsalva reflux from the Left Perineal Point (posterior labial vein). The vulvar tissue is the black dishomogeneous part in the lower half of the picture

All authors have seen and approved the final version of the manuscript being submitted. They warrant that the article is the authors' original work, hasn't received prior publication and isn't under consideration for publication elsewhere.

All authors state that there is no conflict of interest

All authors also state that there was no need to consult an ethics committee because their work consits in an improvment of echo duplex diagnosis, and therapy is represented by simple ligations and venous division in well defined anatomical points.

Authors experience shows the possibility of a low risk but effectiveness and low cost treatment of varicose veins of pelvic origin and therefore the diffusion of the knowledge of this possibility of treatmente is in authors opinion useful for patients.

Authors also consider useful and necessary to the spread the possibility of better and more refined echo duplex diagnosis in order to improve therapeutic strategies.